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EXAMINER
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KAPUSHOC, STEPHEN THOMAS

ART UNIT	PAPER NUMBER
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1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/662,613	<b>Applicant(s)</b> FARID ET AL.	
	<b>Examiner</b> Stephen Kapushoc	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-43,45-50,52-63,65-70,72-74 and 76-80 is/are pending in the application.
- 4a) Of the above claim(s) 11-24,27-43,46-50,52-56,65-70,72-74 and 76-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-10, 25, 26, 45, 57-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 1, 2, 4-43, 45-50, 52-63, 65-70, 72, 73, 74, and 76-80 are pending.

Claims 3, 44, 51, 64, 71, and 75 are cancelled.

Claims 11-24, 27-43, 46-50, 52-56, 65-70, 72-74, and 76-80 are withdrawn.

Claims 1, 2, 4-10, 25, 26, 45, 57-63 are examined on the merits.

This Office Action is in reply to Applicants' correspondence of 12/20/2006.

Claim(s) 3, 44, 51, 64, 71, and 75 is/are cancelled; claim(s) 11-24, 27-43, 46-50, 52-56, 65-70, 72-74, and 76-80 is/are withdrawn; no claim(s) has/have been newly added; claim(s) 1, 7, 25, 45, 57, 59, and 61 has/have been amended.

Applicants' remarks and amendments have been fully and carefully considered but are not found to be sufficient to place this application in condition for allowance. Any new grounds of rejection presented in this Office Action are necessitated by Applicants' amendments. Any rejections or objections not reiterated herein have been withdrawn in light of the amendments to the claims or as discussed in this Office Action.

This Action is made **FINAL**.

### ***Specification and Sequence listing***

1. The amendments to the specification are entered, and as such the previous objection to the specification for containing browser executable code is withdrawn.

Applicants have added SEQ ID NO: 23 to the sequence listing of the instant application. It is noted that basis for the sequence presented as SEQ ID NO: 23 can be found in originally filed SEQ ID NO: 7, as well as Fig 7 of the originally filed specification.

***New grounds of Rejection***  
***Claim Rejections - 35 USC § 112 - 2<sup>nd</sup> Indefiniteness***

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2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is unclear over recitation of the phrase 'said polymorphism is selected from the group consisting of: a single nucleotide polymorphism (SNP), a deletion, and an insertion', because claim 1, from which claim 2 depends, specifies identification of a thymidine at position 3832, which is a single nucleotide polymorphism. It is thus unclear how the required polymorphism can be a deletion or an insertion.

Claim 63 is unclear over recitation of the phrase 'the marker' because there is no antecedent basis for any 'marker' in either claim 63, or claim 57 (from which claim 63 depends).

### **Response to Remarks**

The rejection of claim 45 over recitation of the phrase 'favorable traits associated with reproductive longevity' has been withdrawn. However the breadth of the claim is noted. The claimed method requires a correlation between a thymidine at position 3832 of SEQ ID NO: 23 and any 'favorable' trait, where 'favorable' can be, for example, either increased reproductive longevity or decrease reproductive longevity.

Furthermore, while the claim defines 'reproductive longevity potential', the claim requires screening for traits 'associated with' reproductive longevity potential, and does

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not in fact require screening for reproductive longevity potential. Thus the claim encompasses, for example, associating a thymidine at position 3832 of SEQ ID NO: 23 with a larger uterus in a pig, which may be a trait 'associated with' reproductive longevity potential, for which the specification provides no supporting evidence.

The rejections, as set forth, are MAINTAINED.

***Claim Rejections - 35 USC § 112 1<sup>st</sup> – Written Description***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the revised interim guidelines on written description published January 5, 2001 in the Federal Register, Volume 66, Number 5, page 1099-111 (also available at [www.uspto.gov](http://www.uspto.gov)).

The claims are drawn to methods for screening pigs to determine those more likely to have reproductive longevity potential comprising assaying for the presence of a genotype in the IGF-1R gene at position 3832 of SEQ ID NO: 23. The claims are thus broadly drawn to methods comprising the analysis nucleic acids that are indicative of reproductive longevity and encompass detecting the presence of any genotype, comprised of any nucleic acid sequence, at position 3832 of SEQ ID NO: 23, and thus

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encompass a multitude of different nucleic acid molecules of a wide variety of unique sequences.

When the claims are analyzed in light of the specification, the instant invention encompasses methods comprising the analysis of a large number of nucleic acids comprising a wide variety of nucleic acid sequences. The claims are broadly drawn to any polymorphic variant of an IGF-1R gene (e.g. splice variants, polymorphisms and mutations including single and multiple nucleotide substitution, insertions, deletions, translocations and gene rearrangements) comprising any genotype at position 3832 of SEQ ID NO: 23, which thus encompasses any variants such as SNPs, and deletions and insertions of any number of nucleotides of any sequence.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, relevant to the claimed invention, the specification discloses the nucleic acid sequence of the pig IGF-1R cDNA (SEQ ID NO: 23) and the C/T polymorphism at position 3832. The disclosure does not identify any other nucleotide content or genotype at position 3832 of SEQ ID NO: 23 other than the C/T SNP.

Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case the specification provides no guidance as to how one may identify IGF-1R genotypes at position 3832 of SEQ ID

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NO: 23 other than the C/T SNP variants particularly described in the specification.

There is no guidance as to how to select a polymorphism with the required functionality (i.e. associated with reproductive longevity), as the specification does not provide for how one may *a priori* distinguish a genotype that is indicative with reproductive longevity.

Applicants' attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In the instant application, because of the specific structural information (SEQ ID NO: 23) regarding genotypes in the IGF-1R gene at position 3832 associated with reproductive longevity, one of skill in the art cannot envision the detailed chemical structure of the nucleic acids encompassed by the claimed methods, regardless of the complexity or simplicity of the method of identification. Adequate written description requires more than a mere statement that analysis of such nucleic acids are part of the invention and reference to a potential method for identification. The particular nucleic acids are themselves required.

In conclusion, the limited information provided regarding the particular nucleic acid sequences of the claimed methods is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of methods for analyzing the

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reproductive longevity of pigs by the analysis of any possible genotype at position 3832 of SEQ ID NO: 23.

Thus, having considered the breadth of the claims and the provisions of the specification, it is concluded that the specification does not provide adequate written description for the claims.

### **Response to Remarks**

Applicants have traversed the rejection of claims under 35 USC 112 1<sup>st</sup> ¶ for lack of written description. Applicants assert (p.25 of Remarks) that the claims structurally require a polymorphism at position 3832 of SEQ ID NO: 23. This is not found to be persuasive. As indicated in the rejection as set forth, claims 25 and 26 encompass any 'genotype in the IGF1R gene at position 3832 of SEQ ID NO: 23', and are in no way limited to the particular genotypes or nucleotide content described in the instant specification. The examine maintains that the rejected claims encompass genotypes and nucleic acid sequences not described by the specification that one of skill in the art cannot immediately envision.

The rejection as set forth in MAINTAINED.

### ***Claim Rejections - 35 USC § 112 1<sup>st</sup> Enablement***

6. Claims 11, 2, 4-10, 25, 26, 45, 57-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable



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one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for methods of analyzing the reproductive longevity of a pig comprising assaying for the presence of a polymorphism in the IGF-1R gene at position 3832 of SEQ ID NO: 23.

#### **Nature of the invention and breadth of the claims**

The claims of the instant application are drawn to methods for determining the reproductive longevity of an animal comprising analyzing polymorphisms in the IGF-1R gene at position 3832 of SEQ ID NO: 23.

The claims encompass detection of homozygous and heterozygous genotypes at position 3832 of SEQ ID NO: 23.

Claims 25 and 26 drawn to the detection of a wide variety of polymorphic variants in the IGF-1R gene, encompassing an extremely large number of different types of polymorphisms (e.g. single base or multi-nucleotide transitions and transversions (including silent mutations), any single base or multi-nucleotide insertions or deletions and any type of gene rearrangement) at position 3832 of SEQ ID NO: 23 of the IGF-1R gene

Claim 45 is broadly drawn to a method for screening animals to determine those more likely to exhibit 'favorable traits associated with reproductive longevity', thus the method is drawn to determining a variety of phenotypic traits.

The nature of the claims requires the knowledge of an association between nucleotide content at position 3832 of SEQ ID NO: 23 of a pig IGF-1R gene sequence

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and the reproductive longevity, or traits associated with reproductive longevity, of the animal.

**Direction provided by the specification and working example**

The specification teaches an analysis (p. 52 – Example 2) of the IGF-1R gene sequence in ten pigs: Five living sows with high parity numbers and five animals culled for reproductive reasons representing high reproductive longevity and low reproductive longevity, respectively. And while the specification teaches that ‘reproductive longevity’ means a biologically significant increase in the number of pregnancies and/or the duration of time an animal is capable of reproduction, relative to the mean of a given population, group or species (p.16), the reference does not teach any particular numbers for the parity of the sows used in the example. The reference teaches the identification of five polymorphisms in the pig IGF-1R gene in the ten sows examined, and further teaches that each polymorphism was assayed over a larger sample of animals from the same population to look for evidence of an association with increased reproductive longevity. The specification does not provide any details about this subsequent examination, or any results pertaining to the study.

The specification further teaches an analysis of a polymorphism (indicated as ‘SNP 3832’; a C to T change at position 4889 of SEQ ID NO: 7; Figure 7C) in pigs (Example 3, p.55-56). The specification asserts that ‘Allele 2’ of the gene (T at position 4889 of SEQ ID NO: 7; presence of a FokI site in a fragment amplified with SEQ ID NO: 21 and 22) is positively associated with longevity. However, the specification indicates that in an analysis of 996 sows from four different farms, the determine effect

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is overestimated due to the data structure (p.55, lines 10-11). Example 3 further teaches the association of 'Allele 2' in boars and increased numbers of parities from the sows sired by the boars 'Allele 2'. The specification asserts that there is a positive association between sow homozygosity and reproductive longevity ( $p=0.062$ ), but the specification does not teach that the genotypes of any of the sows in this second study of SNP 3382 was in fact determined.

The specification does not teach any analysis of an association of particular IGF-1R sequences with any traits other than the average number of days from mating to the last parturition in mouse (Example 1), and number of parities and days to culling for reproductive performance in pig (Example 3).

**State of the art, level of skill in the art, and level of unpredictability**

While the state of the art and level of skill in the art with regard to the detection of any particular nucleic acid sequence, or the detection of a polymorphism in a particular sequence is high, the level of unpredictability with regard to associating the presence of a nucleic acid sequence or any particular polymorphism with a phenotype, such as a measure of reproductive longevity, is even higher. The unpredictability is demonstrated by the prior art, the post filing art, and the instant specification.

Because the claims encompass the determination of reproductive longevity by analysis of any polymorphism in the IGF-1R gene of any organism, it is relevant to point out that the art with regard to IGF-1R polymorphisms teaches the breadth of such polymorphisms. NCBI dbSNP teaches that there are 569 SNPs identified in the mouse IGF-1R gene, and GeneCard output for the human IGF-1R teaches that there are 991

SNPS in the human IGF-1R gene; the vast majority of these polymorphisms are not discussed by the specification nor taught by the prior art as being associated with reproductive longevity.

Because the claims encompass methods for determining animals likely to exhibit favorable traits 'associated with reproductive longevity', it is relevant that the post-filing art of Moeller et al (2004) teaches a number of traits that are associated with reproductive productivity (Table 2) for which the specification provides no analysis.

The prior art teaches the unpredictability of using nucleic acid sequence analysis for the determination of a phenotype. For example, Hacker et al (1997) teaches that they were unable to confirm an association between a gene mutation and ulcerative colitis in a case where prior studies suggested such a relationship would exist since the relationship had been identified in a different population (pages 623-627). Additionally, post-filing art reveals that most gene association studies are typically wrong. Lucentini (2004) teaches that it is strikingly common for follow-up studies to find gene-disease associations wrong (left column, 3rd paragraph). Lucentini teaches that two recent studies found that typically when a finding is first published linking a given gene to a disease there is only roughly a one-third chance that the study will reliably confirm the finding (left column, 3rd paragraph). Lucentini teaches that bigger sample sizes and more family-based studies, along with revising statistical methods, should be included in the gene association studies (middle column, 1st complete paragraph).

Even in cases where an association between a particular gene and a phenotypic state is known to exist, such as with the LPL gene and heart disease risk or the  $\beta$ -globin

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gene and sickle cell anemia, researchers have found that when using polymorphism analysis it was difficult to associate SNPs with disease states or to even identify key genes as being associated with disease (Pennisi (1998)). Furthermore, in some cases where multiple polymorphisms are identified in a gene, some of these are demonstrated to be phenotype-associated and some are not. Blumenfeld et al. (WO 99/52942) disclose a number of polymorphisms in the FLAP gene. Blumenfeld et al. were able to demonstrate that some of these polymorphisms are associated with patients having asthma but some of these are not (see Figure 3). For example, the marker 10-35/390 was demonstrated to be associated with asthma, with a p-value of 0.00229, while the marker 10-33/327 was determined to not have a statistical association with asthma ( $p=0.294$ ). Thus, even for mutations within the same gene, it is highly unpredictable as to whether a particular mutation will be associated with a phenotype.

And while the specification asserts an association between the T allele of SNP 3832 and reproductive longevity in the two studies of Example 3, it is relevant to point out that the specification indicates the reported result from the first analysis (using 996 sows) is questionable because of the data structure (p.55, Ins. 10-11). It is also relevant to point out that the analysis of the pig IGF-1R sequence presented in Example 2 does not teach the identification of this position as polymorphic in the pigs examined in Example 2. Additionally, the data presented for the second analysis (using over 19,000 sows from 179 sires) indicates an association with a p-value of  $P=0.062$ . Thus, while the prior art of Thisted (1998) provides guidance as to what is required to indicate that an association is statistically significant (Thisted teaches that it has become scientific

convention to say that a P-value of 0.05 is considered significant (p.5 - What does it mean to be 'statistically significant'), and that values above the conventional reference point of 0.05 would not be considered strong enough for the basis of a conclusion) the instant specification does not teach consistent and significant correlation of SNP 3832 with reproductive longevity in pigs.

It is noted some of the claims do not particularly require the detection of C/T nucleotide content of the pig IGF-1R gene at the SNP 3832 position.

#### **Quantity of experimentation required**

A large and prohibitive amount of experimentation would be required to make and use the claimed invention. Within the scope of the claimed invention, one would have to establish that any nucleotide content at position 3832 of SEQ ID NO: 23 is indicative of any traits 'associated with reproductive longevity potential' in pigs. One would have to perform case:control studies with a large number of animals to determine a statistically significant association between any nucleotide content and reproductive longevity (as determined by a significant increase in the number of pregnancies and/or the duration of time an animal is capable of reproduction, relative to the mean of a given population, group or species) as well as an association with any traits associated with reproductive longevity.

Even for claims that specifically require detection of thymidine at position 3832 of the pig IGF1R gene at of SEQ ID NO: 23, because the specification does not clearly teach a consistent and significant association of this position with reproductive longevity, one would have to perform an analysis of this polymorphic position in any

particular pig population of interest to determine whether or not it is associated with reproductive longevity.

### **Conclusion**

Taking into consideration the factors outlined above, including the nature of the invention and the breadth of the claims, the state of the art, the level of skill in the art and its high level of unpredictability, the amount of guidance by the applicant and the specific working examples, it is the conclusion that an undue amount of experimentation would be required to make and use the claimed invention.

### **Response to Remarks**

Applicants have traversed the rejection of claims under 35 USC 112 1<sup>st</sup> ¶ for lack of enablement. Applicants initially argue (p.26 of Remarks) that the data presented in the specification (p.55 of specification) shows that pigs homozygous for the '2' allele are expected to produce more parities than those pigs that are not homozygous for the '2' allele. However, it is noted that claims 1, 2, 4-10, 25, 26, and 45 do not require detection of homozygosity of the '2' allele (i.e. T at 3832 of SEQ ID NO: 23). Thus such a limitation is not required in the claims.

Further, while applicants argue that the p-values of the first analysis (using 996 sows) are accurate, the specification indicates that the effect on parities is 'overestimated due to the data structure'. Initially it is noted that the data from the first analysis supports a definition of 'reproductive longevity' that requires only the number of pregnancies a pig is capable of, and does not provide evidence of the duration of time a pig is capable of

reproduction. Furthermore, it is not clear how reliable the method is at indicating reproductive longevity if, by the teachings of the specification itself, the data presented is an overestimate.

Applicants additionally argue (p.27 of arguments) that data from the second analysis is enabling for the claimed method. The Examiner maintains that the provided p-value of  $P=0.062$  is not sufficient to consider the results 'statistically significant'. And while applicants argue that a small samples size can influence the p-value of a study, this argument is not considered evidence that, if a larger sample size were analyzed, the results would be significant (i.e. a lower p-value upon analysis of a larger sample). Further it is noted that this second analysis appears to support a definition of 'longevity' only in so far as it applies to the duration of time a pig is capable of reproduction (i.e. 38 days to culling contrast for homozygous sows), and does not address the number of pregnancies a pig is capable of.

Thus given the variables encompassed by the breadth of the claims, and the equivocal nature of the teachings presented in the instant specification, the rejection as set forth in MAINTAINED.

### ***Claim Rejections - 35 USC § 102***

In the rejection of claims under 35 USC 102, as noted in the MPEP 211.02, 'a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone'. Further, in *Pitney Bowes Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1166 (Fed Cir. 1999) the court held that if the body of the claim sets forth the complete invention, and the preamble is not necessary to give "life, meaning and vitality" to the claim, 'then the



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preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation'.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 57 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Harumi et al (2001 as cited in the IDS).

Harumi et al teaches an analysis of the pig IGF-1R gene sequence using RT-PCR analysis of the cDNA sequence, and the identification of polymorphic positions within the sequence.

Regarding claim 57, the reference teaches a method comprising obtaining a sample of genetic material from an animal (p.386, right column, first paragraph), and detecting a polymorphism in the IGF-1R gene of the animal (p.388, left col.; Fig 2). The reference teaches detecting the presence of a T at position 3832 in both copies of the IGF-1R gene (Figure 2, column 6). If, as asserted by the instant application, the presence of a T at position 3832 is indicative of reproductive longevity, then such a property of the nucleotide content at the position is an inherent property of the nucleotide content at the position.

Regarding claim 63, the reference teaches detecting homozygosity of an animal for the 'T' allele of the 3832 SNP. If applicant asserts that this allele of SNP 3832 is positively associated with reproductive longevity, then this positive association is an inherent property of the polymorphism.

### **Response to Remarks**

Applicants have traversed the rejection of claims under 35 USC 102 as anticipated by the prior art of Harumi et al. Applicants argue (p.29 of Remarks) that Harumi et al does not teach the association of a polymorphism with any trait. This is not found to be persuasive, and the required limitations of the rejected claims are noted. The rejected claims merely require detecting a polymorphism, where Harumi et al teaches the detection of the required nucleotide content at the required position of the pig IGF-1R gene. As noted in the rejection, the association of the phenotype with any nucleotide content is an inherent property of the nucleotide content. The claims are not distinguished from the prior art by, for example, a positive process step such as 'inferring that the pig has reproductive longevity based on the presence of thymidine at position 3832 of sid 23 in both copies of the IGF-1R gene'. And while Applicants point out that the instant claims are to methods, and not to compositions of matter, the examiner maintains that in the instant case the method steps required by the claim are taught by the cited reference, and the preamble (reciting a method for genotyping a pig for reproductive longevity potential) is not essential to give completeness to the body of the claim.

The rejection as set forth is MAINTAINED.

***Claim Rejections - 35 USC § 103***

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The rejections under 35 USC 103 as set forth in the previous office action are withdrawn in light of Applicants' amendments to the claims.

### **Conclusion**

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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